UNITED STATES DEPARTMENT OF COMMERCE
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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/111,123	07/06/98	ZAGHOUANI H	ALLIA143

020995 HM22/0103
KNOBBE MARTENS OLSON & BEAR LLP
620 NEWPORT CENTER DRIVE
SIXTEENTH FLOOR
NEWPORT BEACH CA 92660

EXAMINER	
NOLAN, P	
ART UNIT	PAPER NUMBER
1644	15

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

☆U.S.GOVERNMENT PRINTING OFFICE 1995-319-826

Office Action Summary	Application No. 09/111,123	Applicant(s) Zaghouani et al.
	Examiner Nolan	Group Art Unit 1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P riod for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 10/5/00.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disp sition of Claims

☒ Claim(s) 1-7, 8-20 is/are pending in the application.

Of the above claim(s) 8-20 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachm nt(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11, 7

☐ Interview Summary, PTO-413

☒ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Acti n Summary

Part III DETAILED ACTION

1. Claims 1-20 are pending.

2. Claims 8-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, for reasons set forth in Paper No. 5.

3. The request filed on 10-5-00 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/779,767 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:
A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-7 are rejected under 35 U.S.C. § 103 as being unpatentable over Bona et al. (U), of record in view of Kuchroo et al. (6), (IDS) and Karin et al. (X), newly cited.

Bona et al., teaches compositions comprising an immunoglobulin with its CDR3 region replaced by a viral peptide, wherein said fusion protein is endocytosed by cells bearing an Fc receptor, processed by said cells and wherein said cell express said viral

peptides, wherein said viral peptides are T cell peptides which specifically stimulate T cells (abstract, in particular).

The claimed invention differs from the prior art teachings by the recitations of using known T cell receptor antagonists derived from proteolipid or MBP. However, Kuchroo et al., and Karin et al., teach known T cell receptor antagonists derived from myelin proteolipid protein (abstract, in particular) or myelin basic protein (abstract, in particular), autoantigens of the human disease multiple sclerosis. Kuchroo et al., also teaches that analogues derived from known autoimmune epitopes are useful in treating human autoimmune diseases because they compete with the original autoepitope in vivo (page 3330-3331, in particular). Karin et al., teaches the use of a specific peptide antagonist of MBP specific TCR's in reversing EAE, a animal model of human multiple sclerosis. In addition Bona et al., teaches that using Immunoglobulins (IG's) replaced in the CDR3 region are useful in targeting antigens to antigen presenting cells because IG's have longer half lives than synthetic peptides, self-IG's are devoid of side effects and IG's are taken up by various types of APC's via Fc receptors (page 23 in particular). Bona et al., also teaches that the method of delivering antigens to cells via IG's "can be extended to express other biologically important epitopes such as tumor antigens, oncogenes or self antigens which can be used in the antitumor therapy or the therapy of autoimmune diseases. In the later cases, it is possible that the IG bearing epitopes of self antigens will be more efficient for peptide competition therapy envisioned as a novel immunotherapeutic approach of autoimmune diseases" (page 29, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute viral peptide-IG fusion compositions taught by Bona et al., for a known T cell receptor antagonist derived from the autoimmune protein myelin proteolipid taught by Kuchroo et al., or derived from the autoimmune protein myelin basic protein as taught by Karin et al., because peptide-IG fusion compositions are better for delivery of antigens of interest because IG's have longer half lives than synthetic peptides, self-IG's are devoid of side effects and IG's are taken up by various types of APC's via Fc receptors (page 23 in particular), as taught by Bona et al., and said peptide-IG fusion compositions would be useful in the therapy of autoimmune diseases by delivery of peptides for competition therapy as taught by Bona et al., and because Kuchroo et al., or Karin et al.,, teach the successful use of a peptide competitor, (i.e, an analogue) for treating experimental allergic encephalomyelitis, wherein said peptide is derived from myelin proteolipid protein or MBP. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at

the time the invention was made, as evidenced by the references. Furthermore, it would have been obvious to use a combination of both PLP and MBP derived peptides in the Ig-peptide complex because both PLP and MBP peptide analogues were known to treat the same disease EAE and the combination would be obvious to one of ordinary skill in the art. In re Kerkhoven, 205USPQ 1069 (CCPA 1980), recognized that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ... [T]he idea of combining them flows logically from their having being individually taught in the prior art" (see MPEP 2144.06).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 6, 9, 11, 24, 26, 27, 29, 66-70 and 72-73 of copending application Serial No. 08/779,767. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention claimed in claims 4, 6, 9, 11, 24, 26, 27, 29, 66-70 and 72-73 of copending application

Serial No. 08/779,767 are composition claims claiming overlapping subject matter of the invention claimed, product claims, in claims 1-7, of the instant application.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

7. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
January 2, 2001